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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------|---------------------|------------------|
| 09/747,038      | 12/22/2000  | Christopher J. Damien | SBI-078             | 4697             |

7590

04/30/2004

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EXAMINER

BARRETT, THOMAS C

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 04/30/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/747,038

Applicant(s)

DAMIEN, CHRISTOPHER J.

Examiner

Thomas C. Barrett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 4-8, 11-22, 34, 35 and 37 is/are pending in the application.
- 4a) Of the above claim(s) 5-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4, 11-22, 34, 35 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### REQUEST FOR CONTINUED EXAMINATION

The request filed on February 23, 2004 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/747038 is acceptable and a RCE has been established. An action on the RCE follows.

### *Response to Arguments*

Applicant's arguments with respect to claims 4-8, 11-22, 34-35 and 37 have been considered but are moot in view of the new ground(s) of rejection.

### *Specification*

The incorporation of essential material in the specification by reference to a foreign application or patent, or to **a publication** is improper. The Applicant states on page 31, "The disclosures of all patents, patent applications and **printed publications** identified herein are incorporated by reference." There are numerous printed publications cited within the specification, i.e. on page 9.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 4, 11-22, 34-35, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Damien et al. (WO 98/35653). Damien et al. discloses a spinal cage (p 17, lines 22-30) comprising an osteogenic insert paste made of 2-8% purified bovine tendon Type I collagen (p 3, lines 7-10), particulate demineralized bone matrix (p 15, lines 6-8), 10 mM HCL (p 20) and an osteoinductive substance in the form of bone morphogenetic proteins 1-13 (p11, lines 18-29)), which induce osteogenesis in a subject when inserted into disk spaces of lumbar vertebrae (p 17, lines 22-30). Please Note: The Applicant uses the terms "putty and "paste" interchangeably (i.e. p 26, line 19- p 27, line1).

The spinal cage of claim 34 was treated as a "product-by-process" claim. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. The purified collagen of Damien et al. is a moldable osteoinductive and can be placed into a spinal cage as noted above. An argument that the resultant product of the process and the spinal cage of the prior art are not the same requires **evidence** establishing the difference between the claimed product and the prior art product. Please note however that the specification of the present invention discloses that the physical properties of the Applicant's composition "is at least equal to" that of Damien et al.

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (703) 308-8295. The examiner can normally be reached Tuesday-Friday between 9:00 A.M. and 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703) 308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

A handwritten signature in black ink, appearing to read 'Thomas Barrett', with a stylized flourish at the end.

Thomas Barrett